K070945

510(K) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT

Asahi Intecc Co., Ltd.
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Nagoya, Aichi 463-0024
Japan

OFFICIAL CORRESPONDENT

Yoshi Terai
President, CEO
Asahi Intecc USA, Inc.
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JAN - 9 2008

TRADE NAME: ASAHI PTCA Guide Wire

COMMON NAME: Guide Wire

CLASSIFICATION NAME: Catheter Guide Wire

DEVICE CLASSIFICATION: Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE:

K022762	JoWire Neo's PTCA Guide Wire
K031277	JoWire Asahi PTCA Guide Wire
K032615	Asahi PTCA Guide Wire
K041531	Asahi PTCA Guide Wire Confianza
K043422	Asahi PTCA Guide Wire, J Shape Series
K052022	Asahi PTCA Guide Wire, Fielder
K052339	Asahi PTCA Guide Wire
K062186	Asahi PTCA Guide Wire, Fielder J
K063819	Asahi PTCA Guide Wire, Fielder FC

SUMMARY OF SAFETY & EFFECTIVENESS

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi PTCA Guide Wires are steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180 cm and 300 cm length. The extension wire is connected to the end of the guide wire outside the body. The wire is constructed from a stainless steel core wire with varying core lengths and diameters for each design. The core wire and coil are soldered or welded depending upon specific model. The distal end of the guide wire has a radiopaque tip to achieve visibility, and is available straight and is made soft to easily bend with the vessel curve or, available as a pre shaped"J". The coating (hydrophilic and silicone) is applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE. In addition in the fielder series there is polyurethane coating covered with hydrophilic coating applied to the distal section of the guide wire, and the proximal section of this guide wire is coated with PTFE.

INDICATION FOR USE:

The ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel.

TECHNICAL CHARACTERISTICS:

The ASAHI PTCA Guide Wires are of the same materials as the predicate devices with the exception of the modified coating material. The dimensional specifications and design of the device ensures compatibility for the intended use.

PERFORMANCE DATA:

This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI PTCA Guide Wires performs as intended.

SUMMARY/CONCLUSION:

The ASAHI PTCA Guide Wire characteristics with the modified PTFE coating are substantially equivalent to the currently marketed Asahi guidewires for the same indication for use.

Bench testing demonstrates that the device functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

ASAHI Intecc Co., LTD.
c/o Mr. Yoshi Terai
President, CEO
1301 Dove Street, Suite 350
Newport Beach, CA 92660

Re: K070945
Trade Name: Asahi PTCA Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 26, 2007
Received: December 27, 2007

Dear Mr. Terai

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anna R. Uchner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070945

Device Name: ASAHI PTCA Guide Wires

Indications for Use:

The ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lo Richer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070945